

REMARKS

Claims 1, 11, 13, and 17-40 are pending in the present application. Claims 2-10, 12, and 14-16 were previously cancelled.

Applicant would like to thank the Examiner for indicating that claims 36-39 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicant reserves the right to rewrite claims 36-39 in independent form at a later date.

Applicant has carefully reviewed the final Office Action mailed August 10, 2007 and offers the following remarks.

Rejection of Claims 1, 11, 13, 17, 21-35, and 40 Under 35 U.S.C. § 103(a) – Vaschillo & Krebs

Claims 1, 11, 13, 17, 21-35, and 40 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,997,482 to Vaschillo et al. (hereinafter “Vaschillo”) in view of U.S. Patent Application Publication No. 2002/0185126 A1 to Krebs (hereinafter “Krebs”). Applicant respectfully traverses. For the Patent Office to combine references in an obviousness rejection, the Patent Office must establish *prima facie* obviousness by showing where each and every element is taught or suggested in the combined references. MPEP § 2143.03.

Prior to addressing the merits of the rejections, Applicant sets forth a summary of the present invention as claimed. Applicant believes that the Patent Office’s rejection stems in part from a misapplication of Vaschillo to the claimed invention.

The claimed invention facilitates instructing a care patient to synchronize the inhalation and exhalation phases of their breathing cycle with the patient’s heartbeat rate cycle. This assists the patient in attempting to obtain a coherent heart rate variability (HRV) as part of their therapy. HRV is the variation of the natural heartbeat rate cycle. That is, the difference between the minimum and maximum heartbeat rate in the natural heartbeat rate cycle over time. A highly coherent HRV results in consistency in periodicity and amplitude of the natural heartbeat rate cycle over time. An incoherent HRV results from inconsistency in periodicity and amplitude of the natural heartbeat rate cycle over time. A coherent HRV is desired.

A highly coherent HRV is achieved as the breathing cycle of the patient becomes more synchronized with their natural heartbeat rate cycle. A natural heartbeat rate cycle includes

periods of increasing and decreasing heartbeat rate. (Specification, pp. 1-2). This is because natural heartbeat rate tends to increase when inhalation occurs and decrease when exhalation occurs. (*Id.* at p. 2, ll. 1-8). The inventor of the present application recognized that although a heartbeat rate cycle has its own natural variable rhythm, there is a strong correlation between a heartbeat rate cycle and the breathing cycle. (*Id.* at p. 2, ll. 10-19). When the natural heartbeat rate cycle and breathing cycle are misaligned, the resulting HRV is incoherent. However, when the natural heartbeat rate cycle and breathing cycle are aligned, the natural heartbeat rate cycle becomes more consistent. (*Id.* at p. 2, ll. 1-8). This results in a highly coherent HRV. Thus, providing instructions to synchronize breathing cycle with an increasing and decreasing heartbeat rate cycle can assist a patient in aligning their breathing cycle with their natural heartbeat rate cycle to achieve greater consistency in a natural heartbeat rate cycle and in turn a coherent HRV. (*Ibid.*).

In this regard, the claimed invention instructs the care patient of the periods of their increasing and decreasing heartbeat rate. The patient is instructed to synchronize inhalation and exhalation phases of a breathing cycle with the periods of increasing and decreasing heartbeat rate, respectively. Both the breathing cycle and the heartbeat rate cycle are time domain based cycles. Because the patient is also under respiratory therapy, a therapeutic gas is dispensed to the patient as well. To facilitate the patient achieving a highly coherent HRV, the therapeutic gas is dispensed to the patient during the inhalation phase of the breathing cycle based upon the heartbeat rate cycle.

In contrast to the claimed invention, Vaschillo does not detect increases and decreases in heartbeat rate like performed in the claimed invention. Detecting increases and decreases in a heartbeat rate is a time domain based determination since the heartbeat rate occurs in time. Vaschillo cannot anticipate or render obvious the claimed invention, because Vaschillo performs a spectral analysis that is not in the time domain. (see Vaschillo, Abstract). Vaschillo teaches spectrally analyzing a patient's heartbeat and respiratory signals in a passive fashion to generate spectral frequency information for the signals. A phase shift detected in the spectral domain between the heartbeat and the respiratory rates are compared and a phase difference is calculated. The phase difference is used to instruct the patient as opposed to detections of transitions in the natural heartbeat rate cycle like the claimed invention. Because Vaschillo performs its measurement in the spectral domain, it cannot instruct the patient on time periods of increasing

and decreasing heartbeat rate, which is in the time domain, as provided by the claimed invention. Quite simply, Vaschillo could not work to provide the claimed invention, because its spectral system cannot synchronize time periods of increasing and decreasing heartbeat rate and breathing. Thus, Vaschillo cannot teach or suggest the claimed invention. MPEP § 2143.03. One of ordinary skill in the art would not interpret the spectral system of Vaschillo to teach or suggest a synchronization of time periods of increasing and decreasing heartbeat rate. Further, the proposed modification of prior art cannot change the principle of its objection for an obviousness rejection. MPEP § 2143.01.

The claimed invention also requires dispensing a therapeutic gas. Because Vaschillo does not teach or suggest dispensing a therapeutic gas, the Patent Office introduced Krebs to complete the obviousness rejection. Because Vaschillo does not teach or suggest the other limitations of the claimed invention, it is not necessary to address Krebs to overcome the rejection. Accordingly, the Patent Office has not established *prima facie* obviousness.

However, Krebs teaches an artificial respiration gas-supply system for adaptively dosing a gas to individual patients suffering from chronic breathing difficulties, such as asthma and chronic obstructive pulmonary disease (COPD). The system of the Krebs reference controls gas metering to minimize patient side effects from the administered gas. The patient's heart rate and oxygen saturation in the peripheral blood may be measured by use of pulse-oxyimeters to protect the patient from an excessive application of gas. There is no teaching within the Krebs reference of applying therapeutic gas based upon heart rate variability cycle. As such, there is no teaching or suggestion in either Vaschillo or Krebs, either alone or in combination, of dispensing a therapeutic gas to a patient during an inhalation phase of a breathing cycle, synchronized with periods of increasing heartbeat rate of the patient's heartbeat rate cycle.

Rejection of Claims 18-20 Under 35 U.S.C. § 103(a) –
Vaschillo, Krebs & Lutchen

Claims 18-20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Vaschillo in view of Krebs and in further view of U.S. Patent No. 6,435,182 B1 to Lutchen et al. (hereinafter "Lutchen"). Applicant respectfully traverses. The standards for obviousness are set forth above.

Claims 18-20 depend indirectly from claim 1. As such, the rejection of claims 18-20 should be withdrawn for at least the same reasons as claim 1 discussed above. Applicant reserves the right to provide additional arguments against the rejection of claims 18-20 in the future, if needed. Applicant respectfully submits that claims 18-20 are in condition for allowance and notice of the same is requested at the earliest possible date.

The present application is now in condition for allowance and such action is respectfully requested. The Examiner is encouraged to contact Applicant's representative regarding any remaining issues in an effort to expedite allowance and issuance of the present application.

Respectfully submitted,

WITHROW & TERRANOVA, P.L.L.C.

By:



Steven N. Terranova
Registration No. 43,185
100 Regency Forest Drive, Suite 160
Cary, NC 27518
Telephone: (919) 238-2300

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